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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/936,527 | 09/14/2001 | Karl Reuter | 033265-003 | 4392 |

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EXAMINER

KUHAR, ANTHONY J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1754 | <i>5</i> |

DATE MAILED: 10/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/936,527 | REUTER, KARL |
| | Examiner | Art Unit |
| | Anthony J Kuhar | 1754 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM

THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 1-10 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the crystals" in step d. There is insufficient antecedent basis for this limitation in the claim.

In claim 5, "accordingly" is ungrammatical.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/32644.

A process for crystallization is taught in WO 97/32644 where impure crystals are dispersed in one or more solvents (see page 3, lines 31-32). Organic liquids for the solvents are taught on page 5. A second phase is also taught, which can be water (see page 5, line 5). The

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second phase is dispersed into the first phase or vice versa and the emulsion supersaturated (see page 14, lines 13-23). Forming microemulsions are taught on page 3, lines 1-15. Subsequent crystallization is taught on page 10, lines 1-4. The crystallization process can be further optimized by stirring, shaking, or ultrasound. Temperature adjustment is also taught on page 12, line 32. Isolating and washing the crystals, possibly with a surfactant, is taught on page 14, lines 1-10. Page 16, lines 28-35 teach recycling the emulsion after crystals are filtered and reloading the emulsion. Page 15, lines 26-33 teach this as a continuous process as it is repeated with the recycled emulsion (see page 17, lines 1-5).

Claims 1-2, 4-6, and 8-10 rejected under 35 U.S.C. 102(b) as being anticipated by Reuter '259.

Reuter '259 teaches a mixture of stereoisomers being dissolved in an organic solvent, with the optional aid of ultrasound, shear equipment (mixing), or heating (see column 5, lines 5-9). The "oil phase" is emulsified into a water phase (see column 5, lines 26-31). Supersaturation is further taught in column 5, line 10. Seeding is taught of the pure stereoisomer in column 5, lines 33-37; thus, the other stereoisomers are considered the impurity. Column 6, lines 42-48 teach a continuous process where the emulsion is filtered and reloaded and the previous steps repeated. The crystals are washed with water in the examples.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reuter '259 in view of WO' 97/32644 and Marsh '743.

Reuter '259 teaches a mixture of stereoisomers being dissolved in an organic solvent, with the optional aid of ultrasound, shear equipment (mixing), or heating (see column 5, lines 5-9). The "oil phase" is emulsified into a water phase (see column 5, lines 26-31). Supersaturation is further taught in column 5, line 10. Seeding is taught of the pure stereoisomer in column 5, lines 33-37; thus, the other stereoisomers are considered the impurity. Column 6, lines 42-48 teach a continuous process where the emulsion is filtered and reloaded and the previous steps repeated. The crystals are washed with water in the examples. Reuter does not teach microemulsions nor washing while centrifuging.

However, WO 97/32644 teaches, in a similar process for crystallization, forming microemulsions on page 3, lines 1-15. At the time the invention was made, it would have been obvious for one of ordinary skill in the art to use the process of Reuter '259 to synthesize pure

crystals while forming microemulsions during the process using the teachings of WO /9732644 because the WO reference teaches microemulsions provide the advantage of being able to observe and monitor crystallization and also there is a larger surface area for crystals to move from the first phase to the second phase, the improved crystallization rates are realized (see page 3, lines 1-12). One of ordinary skill in the art would have been motivated to do this because improved crystallization rate are advantageous from the points of scale-up and commercialization (see page 3, lines 11-12).

In addition, Marsh '743 teaches centrifuging while washing the crystals on page 5, lines 34-37. At the time the invention was made, it would have been obvious for one of ordinary skill in the art to use the process of Reuter '259 and further optimize it using the teachings of Marsh '743 because the Marsh reference teaches that this results in impurities being washed into the mother liquor of the crystallization process and purer crystals obtained (see column 5, lines 40-43). One of ordinary skill in the art would have been motivated to do this because obtaining purer crystals further accomplishes the desired quality of the crystals obtained.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO' 97/32644 in view of Marsh '743.

A process for crystallization is taught in WO 97/32644 where impure crystals are dispersed in one or more solvents (see page 3, lines 31-32). Organic liquids for the solvents are taught on page 5. A second phase is also taught, which can be water (see page 5, line 5). The second phase is dispersed into the first phase or vice versa and the emulsion supersaturated (see page 14, lines 13-23). Forming microemulsions are taught on page 3, lines 1-15. Subsequent

crystallization is taught on page 10, lines 1-4. The crystallization process can be further optimized by stirring, shaking, or ultrasound. Temperature adjustment is also taught on page 12, line 32. Isolating and washing the crystals, possibly with a surfactant, is taught on page 14, lines 1-10. Page 16, lines 28-35 teach recycling the emulsion after crystals are filtered and reloading the emulsion. Page 15, lines 26-33 teach this as a continuous process as it is repeated with the recycled emulsion (see page 17, lines 1-5). The WO reference does not teach washing the crystals during centrifuging.

However, Marsh '743 teaches centrifuging while washing the crystals on page 5, lines 34-37. At the time the invention was made, it would have been obvious for one of ordinary skill in the art to use the process of Reuter '259 and further optimize it using the teachings of Marsh '743 because the Marsh reference teaches that this results in impurities being washed into the mother liquor of the crystallization process and purer crystals obtained (see column 5, lines 40-43). One of ordinary skill in the art would have been motivated to do this because obtaining purer crystals further accomplishes the desired quality of the crystals obtained.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anthony J Kuhar whose telephone number is 703-305-7095. The examiner can normally be reached on 8:00 am - 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stan Silverman can be reached on 703-308-3837. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-305-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

AK
AK

October 2, 2002

SJB~

STEVEN BOS
PRIMARY EXAMINER
GROUP 1100